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### Remarks

Applicants respectfully request reconsideration of this application in view of the following remarks.

### Status of the Claims

Claims 41-51 are pending in this application. No amendments to the claims have been made in this response and therefore, Claims 41-51 remain pending for examination on the merits.

## Restriction Requirement

In the pending Office Action, Applicants' election with traverse of Group I,
Claims 41-42, was acknowledged and the restriction requirement was made final.
According to 37 C.F.R. §1.144, Applicants have thus preserved their right to petition the
Commissioner to review the restriction requirement.

# Rejection of Claims 41-42 under 35 U.S.C. §101

Claims 41-42 were rejected under 35 U.S.C. §101 over Claims 13-14 of US 6,653,323. Applicants respectfully traverse the rejection.

As discussed, for example, in MPEP §706.03(a), 35 U.S.C. §101 defines subject matter and utility requirements for patentability. Present Claims 41-42 recite a pharmaceutical composition comprising a pharmaceutically-acceptable carrier and a specific chemical compound. Claims 41-42 are directed to a statutory class of subject matter, namely "composition of matter", having a well-defined utility, and thus satisfy the above requirements of 35 U.S.C. §101.

In addition, 35 U.S.C. §101 provides the statutory basis for a double patenting rejection of the "same invention" type. According to MPEP §804 (II)(A), "same invention" means identical subject matter:

Is there an embodiment of the invention that falls within the scope of one claim but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

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In the present instance, Claims 41 and 42 are directed to a pharmaceutical composition comprising a specific chemical compound, N-{2-[4-(3-phenyl-4-methoxyphenyl)aminophenyl]ethyl}-(R)-2-hydroxy-2-(8-hydroxy-2(1H)-quinolinon-5-yl)ethylamine. In contrast Claims 13 and 14 of US 6,653,323 read on a pharmaceutical composition comprising any one of a number of chemical compounds defined by formulas (I) and (IV) therein, only one of which is N-{2-[4-(3-phenyl-4-methoxyphenyl)aminophenyl]ethyl}-(R)-2-hydroxy-2-(8-hydroxy-2(1H)-quinolinon-5-yl)ethylamine, the compound recited in present Claims 41 and 42. There exist, therefore, embodiments of Claims 13 and 14 of US 6,653,323 that do not fall within the scope of the instant claims. Accordingly a statutory double patenting rejection of the instant claims over Claims 13 and 14 of US 6,653,323 does not exist.

In view of the foregoing, Applicants respectfully submit the rejection of Claims 41 and 42 under 35 U.S.C. §101 may be withdrawn.

# Rejections under Obviousness-type Double Patenting

Claims 41-42 were rejected under the judicially created doctrine of obviousness-type double patenting over Claims 30-31 of U.S. Patent No. 6,670,376. In response, Applicants are submitting herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321(c). Accordingly, this rejection may be withdrawn

Applicants note that the filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection.

Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20

USPQ2d 1392 (Fed. Cir. 1991). Specifically, the courts have indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

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### Conclusion

Reconsideration of this application in view of the above remarks is respectfully requested. Should there be any issues regarding this application that can be resolved by telephone, the examiner is invited to telephone the undersigned agent for Applicants at (650) 808-3764 (direct).

Respectfully submitted,

THERAVANCE, INC.

Date: April 5, 2005

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